Epic International (Thailand) Co., Ltd.

EPIC INTERNATIONAL (THAILAND) CO., LTD. is a leading company in the design and manufacture of medical devices in the infusion therapy space for both hospital-based sites and home care environment. We are driven by our purpose of a *Being Relevant* enterprise, aiming to be recognized by health care communities worldwide as a global innovative company, delivering value devices and solutions with the highest safety and quality standard.

The manufacturing facility is located at Hemaraj Eastern Seaboard Industrial Estate in Rayong. We offer attractive job opportunities with very high prospects for career development. The following positions are now open.

To apply, please submit your resume to Kenneth Teo at kenneth.teo@epic-med.com.

QA/RA Manager

Responsibilities:

- The QA and QC Managerial position comprises of QA Program and QC Operation roles, has responsibility over the assurance of product quality as part of the Quality Strategy to assure the achievement of product performance and safety specifications as well as the effective implementation of the quality management system.
- All quality processes carried out in the manufacture of the product namely vendor qualification, raw material and input inspections, in-process and final release inspection, including sterilization and DHR release, calibration of IMT equipment and process measuring equipment, validation coordination and testing support control of validated process
- Support in Document Control, Improvement Processes that includes Nonconformance Action, Corrective and Preventive Actions, Product Complaint Handling, Field Actions and Post-market Surveillance.

Major Duties and Performance Standards to be Achieved:

- To execute the medium and long-term strategic quality plan and operate the established quality management concept.
- To manage regulatory audit/inspection preparation as well as internal Quality audits
- To always act with focus on the quality objectives to achieve actions that are aligned with the Principles set in the Company's GMP Manual.
- To carry out responsibilities in strict compliance with relevant statutory and regulatory requirements relevant to the business.

- Investigation and reporting of all customer complaints, adverse field events in accordance to the necessary Medical Device Reporting Regulations.

Experience/Knowledge Required:

- More than 5 years' experience as a Senior/ Principal Quality Engineer / Quality Manager in the medical device/ medical service industry.
- Familiar or have worked with US FDA 21 CFR 820, EU MDD 93/42/EEC.
- Had been a Quality Management Representative.

Special Skills/Abilities Required:

- US FDA Current Good Manufacturing Practice (CGMP)
- Lead auditor for QMS, preferably ISO 13485.
- MDD Risk Management, CE Marking of Medical Devices and ISO 14971.
- Excellent command of English (verbal and written).